Prepared Statement of
The Federal Trade Commission

Before the

Committee on Commerce, Science, and Transportation
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I. Introduction

Mr. Chairman, I am Timothy J. Muris, Chairman of the Federal Trade Commission. I am pleased to appear before the Committee today to testify on behalf of the Commission regarding competition in the pharmaceutical industry.[1]

Advances in the pharmaceutical industry continue to bring enormous benefits to Americans. Because of pharmaceutical innovations, a growing number of medical conditions often can be treated more effectively with drugs and drug therapy than with alternative means (e.g., surgery). The development of new drugs is risky and costly, however, which has an impact on the prices of prescription drugs. Likewise, the development of generic drugs also can be risky and costly. Expenditures on pharmaceutical products continue to grow. According to the Employee Benefit Research Institute, such expenditures increased 92 percent over the past five years, to $116.9 billion.[2] Pharmaceutical expenditures are thus a concern not only to individual consumers, but to government payers, private health plans, and employers as well.

To address the issue of escalating drug expenditures, and to ensure that the benefits of pharmaceutical innovation would be available to the broadest group of healthcare consumers possible,

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[1] The written statement represents the views of the Federal Trade Commission. My oral presentation and responses are my own and do not necessarily reflect the views of the Commission or of any other Commissioner.

[2] Milt Freudenheim and Melody Peterson, *The Drug Price Express Runs into a Wall*, N.Y. Times, Dec. 23, 2001.

[3] Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)).

[4] 21 U.S.C. § 301 *et seq*.

Congress passed the Hatch-Waxman Amendments[3] to the Food, Drug and Cosmetic Act ("FDC Act").[4] The Hatch-Waxman Amendments were intended to promote robust competition in the pharmaceutical industry and, to a large degree, have succeeded.[5] The Congressional Budget Office estimates that, by purchasing generic equivalents of brand name drugs, consumers saved $8-10 billion on retail purchases of prescription drugs in 1994 alone.[6] With patents on branded drugs having combined U.S. sales of almost $20 billion set to expire within the next four years,[7] these already substantial savings are likely to increase dramatically.

Yet, in spite of this remarkable record of success, the Hatch-Waxman Amendments have also been subject to abuse. Although many drug manufacturers – including both branded companies and generics – have acted in good faith, some have attempted to "game" the system, securing greater profits for themselves without providing a corresponding benefit to consumers. It is these anticompetitive efforts that the Federal Trade Commission has addressed. The nature of that response, both past and present, is the principal subject of this testimony.

Over time, the Commission has developed significant expertise regarding competition in the pharmaceutical industry. The Commission has, for example, brought antitrust enforcement actions affecting both branded and generic drug manufacturers.[8] The Commission has also conducted empirical analyses of competition in the pharmaceutical industry, including in-depth studies by the staff of the Bureau of Economics.[9] The Commission's efforts have included filing comments with the Food and Drug Administration ("FDA") regarding the competitive aspects of Hatch-Waxman implementation,[10] as

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[3] Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)).

[4] 21 U.S.C. § 301 *et seq*.

[5] The Hatch-Waxman Amendments also were intended to encourage pharmaceutical innovation through patent term extensions. *See infra* note 14 and accompanying text.

[6] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998) ("CBO Study"), *available at* <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0>.

[7] *Id.* at 3. *See also* Amy Barrett, *Crunch Time in Pill Land*, Business Week 52 (Nov. 22, 1999).

[8] *See, e.g., FTC v. Mylan Laboratories, Inc. et al*., 62 F. Supp. 2d 25 (D.D.C. 1999); *Roche Holding Ltd.*, 125 F.T.C. 919 (1998) (consent order); *Ciba-Geigy Ltd.*, 123 F.T.C. 842 (1997) (consent order).

[9] Bureau of Economics Staff Report, Federal Trade Commission, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* (Mar. 1999) *available at* <http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf>; David Reiffen and Michael R. Ward, *Generic Drug Industry Dynamics*, Bureau of Economics Working Paper No. 248 (Feb. 2002) ("Reiffen and Ward"), *available at* <http://www.ftc.gov/be/econwork.htm>.

[10] *FDA: Citizen Petition*, Comment of the Staff of the Bureau of Competition and of Policy

well as previous testimony before Congress.[11] Furthermore, individual Commissioners have addressed the subject of pharmaceutical competition before a variety of audiences, both to solicit input from affected parties and to promote dialogue regarding practical solutions.[12]

The subject of this testimony, however, is more limited. This testimony addresses the Commission's efforts to ensure efficient operation of the Hatch-Waxman process directly through vigorous enforcement of the antitrust laws. To date, these efforts principally have entailed litigation relating to settlements between brands and generics alleged to be anticompetitive; this testimony refers to those as "first generation litigation." More recently, the Commission has progressed to "second generation litigation," involving issues such as allegedly improper Orange Book listings. We are also examining potentially anticompetitive settlements between generics themselves. This testimony will also briefly address the Commission's non-litigation efforts, which include an ongoing industry-wide study of pharmaceutical competition, as well as continuing inter-agency discussions with the FDA.

Planning of the Federal Trade Commission Before the Food and Drug Administration (Mar. 2, 2000) *available at* <http://www.ftc.gov/be/v000005.pdf> (recommending modifications to the FDA's Proposed Rule on citizen petitions intended to discourage anticompetitive abuses of the FDA's regulatory processes); *FDA: 180-Day Marketing Exclusivity for Generic Drugs*, Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration (Nov. 4, 1999) ("Marketing Exclusivity Comment") *available at* <http://www.ftc.gov/be/v990016.htm> (recommending that the FDA's Proposed Rule on 180-day marketing exclusivity be modified to limit exclusivity to the first ANDA filer and to require filing of patent litigation settlement agreements).

[11] Testimony of Federal Trade Commission before the Committee on the Judiciary, United States Senate, *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements* (May 24, 2001) *available at* <http://www.ftc.gov/os/2001/05/pharmtstmy.htm>.

[12] *See, e.g.*, Sheila F. Anthony, *Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property* (June 1, 2000) *available at* <http://www.ftc.gov/speeches/anthony/sfip000601.htm>; Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes* (Nov. 3, 2000) *available at* <http://www.ftc.gov/speeches/leary/learypharma.htm>; Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II* (May 17, 2001) *available at* <http://www.ftc.gov/speeches/leary/learypharmaceutical settlement.htm>; Timothy J. Muris, *Competition and Intellectual Property Policy: The Way Ahead*, at 5-6 (Nov. 15, 2001) *available at* <http://www.ftc.gov/speeches/muris/intellectual.htm>.

II. Regulatory Background: The Hatch-Waxman Drug Approval Process

A. The Hatch-Waxman Balance

The stated purpose of the Hatch-Waxman Amendments is to "make available more low cost generic drugs."[13] The concern that the FDA's lengthy drug approval process was unduly delaying market entry by low-cost generic versions of brand-name prescription drugs motivated Congress's passage of the Amendments. Because a generic drug manufacturer was required to obtain FDA approval before selling its product, and could not begin the approval process until any conflicting patents on the relevant branded product expired, the FDA approval process essentially functioned to extend the term of the branded manufacturer's patent monopoly. To correct this problem, Congress provided in the Amendments that certain conduct related to obtaining FDA approval, which would otherwise constitute patent infringement, would be exempted from the patent laws.

This limited objective, however, was in no way intended to undermine fundamental intellectual property rights. Congress continued to regard patent protection as critical to pharmaceutical innovation, and as an important priority in its own right. The Hatch-Waxman Amendments thus represented a compromise: an expedited FDA approval process to speed generic entry balanced by additional intellectual property protections to ensure continuing innovation. As one federal appellate judge explained, the Amendments "emerged from Congress's efforts to balance two conflicting policy objectives: to induce brand-name pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."[14]

Pursuant to the FDC Act, a branded drug manufacturer seeking to market a new drug product must first obtain FDA approval by filing a New Drug Application ("NDA"). At the time the NDA is filed, the NDA filer must also provide the FDA with certain categories of information regarding patents that cover the drug that is the subject of its NDA.[15] Upon receipt of the patent information, the FDA is required to list it in an agency publication entitled "Approved Drug Products with Therapeutic Equivalence," commonly known as the "Orange Book."[16]

Rather than requiring a generic manufacturer to repeat the costly and time-consuming NDA process, the Amendments permit the company to file an Abbreviated New Drug Application ("ANDA"), which incorporates data that the "pioneer" manufacturer has already submitted to the FDA regarding the branded drug's safety and efficacy. The object of the ANDA process is to demonstrate

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[13] H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

[14] *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting) (citations omitted).

[15] 21 U.S.C. § 355(b)(1).

[16] *Id.* at § 355(j)(7)(A).

that the generic drug is "bioequivalent" to the relevant branded product.[17] The ANDA must contain, among other things, a certification regarding each patent listed in the Orange Book in conjunction with the relevant NDA.[18] One way to satisfy this requirement is to provide a "Paragraph IV certification," asserting that the patent in question is invalid or not infringed.[19]

Filing a Paragraph IV certification potentially has significant regulatory implications, as it is a prerequisite to operation of two significant provisions of the statute. The first of these is the automatic "30-month stay" protection afforded patents. An ANDA filer that makes a Paragraph IV certification must provide notice, including a detailed statement of the factual and legal basis for the ANDA filer's assertion that the patent is invalid or not infringed, to both the patent holder and the NDA filer.[20] Once the ANDA filer has provided such notice, a patent holder wishing to take advantage of the statutory stay provision must bring an infringement suit within 45 days.[21] If the patent holder does not bring suit within 45 days, the FDA must approve the ANDA immediately, if other regulatory conditions are fulfilled.[22] If the patent holder does bring suit, however, the filing of that suit triggers an automatic 30-month stay of FDA approval of the ANDA.[23] During this period, unless the patent litigation is resolved in the generic's favor, the generic cannot enter the market.

The second significant component of the Hatch-Waxman Amendments is the "180-day period of exclusivity." The Amendments provide that the first generic manufacturer to file an ANDA containing a Paragraph IV certification is awarded 180 days of marketing exclusivity, during which the FDA may not approve a potential competitor's ANDA.[24] Through this 180-day provision, the Amendments provide an incentive for companies to challenge patents and develop alternative forms of patented drugs.[25] The 180-day period is calculated from the date of the first commercial marketing of the generic drug product or the date of a court decision declaring the patent invalid or not infringed, whichever is sooner.[26] The 180-day exclusivity period increases the economic incentives for a generic company to

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[17] *Id.* at § 355(j)(2)(A)(iv).

[18] *Id.* at § 355(j)(2)(A)(vii).

[19] *Id.* at § 355(j)(2)(A)(vii)(IV).

[20] *Id.* at § 355(j)(2)(B). Although the patent holder and the NDA filer are often the same person, this is not always the case. The Hatch-Waxman Amendments require that all patents that claim the drug described in an NDA must be listed in the Orange Book. Occasionally, this requires an NDA filer to list a patent that it does not own.

[21] *Id.* at § 355(j)(5)(B)(iii).

[22] *Id.* For example, the statute requires the ANDA applicant to establish bioequivalence. *See supra* note 17.

[23] 21 U.S.C. at § 355(j)(5)(B)(iii).

[24] *Id.* at § 355(j)(5)(B)(iv).

[25] *See Granutec, Inc. v. Shalala*, 139 F.3d 889, 891 (4th Cir. 1998).

[26] 21 U.S.C. § 355(j)(5)(B)(iv).

[27] There has been litigation over what acts trigger the 180-day period of exclusivity. *See infra*

be the first to file an ANDA and get to market.[27] Of course, during the 180 days, the generic would compete with the branded product. After the 180 days, subject to regulatory approvals and determination of the outcomes of any patent suits, other generics can enter the market.

B. Competitive Implications

The "30-month stay" and the "180-day period of exclusivity" were both a part of the Hatch-Waxman balance. The imposition of a stay in some cases could forestall generic competition for a substantial period of time. The 180-day period of exclusivity can, in some circumstances, limit the number of generic competitors during this period.[28] Over the past few years we have learned that some branded and generic drug manufacturers have "gamed" the system, attempting to restrict competition beyond what the Hatch-Waxman Amendments intended. This testimony will now discuss our efforts to investigate vigorously and to prosecute such abuses.

III. Promoting Competition through Antitrust Enforcement

A. First Generation FTC Litigation: Settlements Between Brands and Generics

Studies of the pharmaceutical industry indicate that the first generic competitor typically enters the market at a significantly lower price than its branded counterpart, and gains substantial share from the branded product.[29] Subsequent generic entrants typically bring prices down even further.[30] The policies of many health plans, both public and private, which require generic substitution whenever possible, accelerate this trend. These are the consumer benefits of the competition that the Hatch-Waxman Amendments were meant to facilitate. This competition substantially erodes the profits of branded pharmaceutical products. Although successful generics are profitable, their gain is substantially less than the loss of profits by the branded product, because of the difference in prices between branded and generic products. As a result, both parties can have economic incentives to collude to delay generic entry. By blocking entry, the branded manufacturer can preserve its monopoly profits. A portion of these profits, in turn, can be used to fund payments to the generic manufacturer to induce it to forgo the profits it could have realized by selling its product. Furthermore, by delaying the first generic's entry – and with it, the triggering of the 180 days of exclusivity – the branded and first-filing generic firms can sometimes forestall the entry of other generics. Patent infringement litigation settlement agreements between the branded manufacturer and the first-filing generic could be one method to effect such a collusive scheme.

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note 63.

[28] These circumstances occur when other generic firms had products ready to market, were tentatively approved by the FDA, and were not impeded by patent litigation.

[29] *See* CBO Study, *supra* note 6; *see generally* Reiffen and Ward, *supra* note 9.

[30] *See* CBO Study, *supra* note 6; Reiffen and Ward, *supra* note 9, at 4.

The Commission's first generation litigation focused on patent settlement agreements between brands and generics that the Commission alleged had delayed the entry of one or more generics. Resolving patent infringement litigation through settlement can be efficient and procompetitive. Certain patent settlements between brands and generics, however, drew the Commission's attention when it appeared that their terms may have maintained monopolies through abuses of the Hatch-Waxman regime.

Two leading cases illustrate the Commission's efforts in the area: *Abbott/Geneva* and *Hoechst/Andrx*. The first of these cases involved an agreement between Abbott Laboratories and Geneva Pharmaceuticals, Inc. relating to Abbott's branded drug Hytrin. The Commission's complaint alleged that Abbott paid Geneva approximately $4.5 million per month to delay the entry of its generic Hytrin product, potentially costing consumers hundreds of millions of dollars a year.[31] The complaint further alleged that Geneva agreed not to enter the market with *any* generic Hytrin product – including a non-infringing product – until: (1) final resolution of the patent infringement litigation involving Geneva's generic Hytrin tablets, or (2) market entry by another generic Hytrin manufacturer. Geneva also allegedly agreed not to transfer its 180-day marketing exclusivity rights.

The second case involved an agreement between Hoechst Marion Roussel and Andrx Corp. relating to Hoechst's branded drug Cardizem CD. The Commission's complaint alleged that Hoechst paid Andrx over $80 million, during the pendency of patent litigation, to refrain from entering the market with its generic Cardizem CD product.[32] As in the *Abbott/Geneva* case, the Commission also asserted that the agreement called for Andrx, as the first ANDA filer, to use its 180-day exclusivity rights to impede entry by other generic competitors.

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[31] *Abbott Laboratories*, No. C-3945 (May 22, 2000) (consent order), complaint *available at* <http://www.ftc.gov/os/2000/05/c3945complaint.htm>, and *Geneva Pharmaceuticals, Inc.*, No. C-3946 (May 22, 2000) (consent order), complaint *available at* <http://www.ftc.gov/os/2000/05/c3946complaint.htm>.

[32] *See Hoechst Marion Roussel, Inc.*, No. 9293 (May 8, 2001) (consent order), complaint *available at* <http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm>.

[33] The consent order in *Abbott Laboratories* is available at <http://www.ftc.gov/os/2000/03/abbot.do.htm>. The consent order in *Geneva Pharmaceuticals* is available at <http://www.ftc.gov/os/2000/03/genevad&o.htm>. The consent order in *Hoechst/Andrx* is available at <http://www.ftc.gov/os/2001/05/hoechstdo.pdf>. Similar issues are raised by another case – *Schering-Plough* – that is still in litigation. *See Schering-Plough Corp.*, No. 9297 (complaint issued Mar. 30, 2001), *available at* <http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf>. On April 2, 2002, the Commission resolved all claims against one of the three respondents, American Home Products ("AHP"), by issuing a final consent order. Pursuant to that order, AHP is prohibited from

Both cases were resolved by consent order.[33] The orders prohibited the respondent companies from entering into brand/generic agreements pursuant to which a generic company that is the first ANDA filer with respect to a particular drug agrees not to: (1) enter the market with a non-infringing product, or (2) transfer its 180-day marketing exclusivity rights. In addition, the companies were required to obtain court approval for any agreements made in the context of an interim settlement of a patent infringement action, that provided for payments to the generic to stay off the market, with advance notice to the Commission to allow it time to present its views to the court. Advance notice to the Commission was also required before the respondents could enter into such agreements in non-litigation contexts.

Although the specific terms of the brand/generic settlement agreements challenged by the Commission in these two cases were particular to these cases, the cases highlight the Commission's concern about settlements whose primary effect appears to be to *delay generic entry*, leading to less vigorous competition and higher prices for consumers. Of course, not all settlements are problematic. While the Commission has not attempted to set forth a comprehensive list of potentially objectionable settlement provisions, it is possible to identify from the Commission's reported cases a few types of provisions that, within the Hatch-Waxman context, have drawn antitrust scrutiny. These include:

- *Provisions that provide for "reverse" payments.* "Reverse" payments (*i.e.*, payments from the patent holder to the alleged infringer) may merit antitrust scrutiny, since they may represent an anticompetitive division of monopoly profits.

- *Provisions that restrict the generic's ability to enter with non-infringing products.* Such provisions can extend the boundaries of the patent monopoly without providing any additional public disclosure or incentive to innovate, and therefore have the potential to run afoul of the principles of antitrust law.[34]

- *Provisions that restrict the generic's ability to assign or waive its 180-day marketing exclusivity rights.* Because a second ANDA filer may not enter the market until the first filer's 180-day period of marketing exclusivity has expired, restrictions on assignment or waiver of the exclusivity period can function as a

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entering into two categories of agreements: (1) those in which the brand makes a payment to the generic in return for delayed entry, and (2) those in which the generic agrees not to enter the market with a non-infringing product. *See Schering-Plough Corp.*, No. 9297 (consent order as to AHP issued Apr. 2, 2002), *available at* <http://www.ftc.gov/os/2002/04/scheringplough_do.htm>.

[34] *Cf. Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964) (holding that "enlarg[ing] the monopoly of the patent" by collecting post-expiration royalties constitutes patent misuse).

[35] *But see* Leary, Part II, *supra* note 12, at 7 (arguing that agreements regarding waiver of 180-day exclusivity period may have no anticompetitive effect absent reverse payment).

bottleneck, potentially delaying subsequent generic entry for an extended period.[35]

B. Second Generation FTC Litigation: Improper Orange Book Listings

1. *In re Buspirone*

One of the principal focuses of the Commission's second generation litigation has been improper Orange Book listings.[36] Unlike the settlement cases discussed above, which typically involve collusion between private parties, an improper Orange Book listing strategy involves abuse of the Hatch-Waxman process itself to restrain trade. Such conduct has raised *Noerr-Pennington* issues – an area of longstanding Commission interest.

The *Noerr* doctrine – first articulated as an interpretation of the Sherman Act in *Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*[37] and *United Mine Workers of America v. Pennington*[38] – provides antitrust immunity for individuals "petitioning" government. While the *Noerr* doctrine is an important limitation on the antitrust laws that protects the right of individuals to communicate with government entities, some courts have interpreted the doctrine too broadly in ways that are inconsistent with Supreme Court precedent. The *Noerr* doctrine was never intended to protect what Robert Bork has characterized as "[p]redation through the misuse of government processes."[89]

One matter that arose from such a "misuse of government processes" was the Commission's *U-Haul* case.[40] That case involved a bankruptcy situation in which U-Haul, as a creditor, was presented with an opportunity to participate in the reorganization of its largest competitor. Rather than

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[35] *But see* Leary, Part II, *supra* note 12, at 7 (arguing that agreements regarding waiver of 180-day exclusivity period may have no anticompetitive effect absent reverse payment).

[36] The Commission first raised concerns about the potential anticompetitive impact of improper Orange Book listings in *American Bioscience, Inc. v. Bristol-Myers Squibb Co., et al.*, Dkt. No. CV-00-08577 (C.D. Cal. Sept. 7, 2000). *See* Federal Trade Commission Brief as *amicus curiae available at* <http://www.ftc.gov/os/2000/09/amicusbrief.pdf>. In that case, the parties sought court approval of a settlement containing a specific factual finding that Bristol-Myers was required to list American Bioscience's patent of Bristol-Myers's branded drug Taxol in the Orange Book. The Commission was concerned that the court's approval of the settlement would amount to a judicial finding that the patent met the statutory requirements for listing in the Orange Book and would prejudice parties who may later challenge the listing.

[37] 365 U.S. 127 (1961).

[38] 381 U.S. 657 (1965).

[39] Robert H. Bork, The Antitrust Paradox: A Policy at War with Itself 364 (Free Press 1993) (1978).

[40] *AMERCO, et al.*, 109 F.T.C. 135 (1987).

acting in good faith, the Commission alleged, U-Haul used the bankruptcy proceeding to undermine its rival and sought to delay the reorganization in a plainly anticompetitive manner.

To address the concern that *Noerr* doctrine was being interpreted too expansively, potentially resulting in the extension of immunity to misuses of government processes, we convened a *Noerr-Pennington* Task Force of Commission staff in June 2001. One of the objectives of the Task Force was to clarify existing aspects of the *Noerr* doctrine, such as the scope of "petitioning" conduct and the continuing existence of a misrepresentation exception to *Noerr* immunity. Another was to identify ongoing misuses of governmental processes that would potentially subject the participants to antitrust liability.

One of the first potential abuses the Task Force considered was the improper listing of patents in the FDA's Orange Book. Pursuant to current policy, the FDA does not review patents presented for listing in the Orange Book to determine whether they do, in fact, claim the drug product described in the relevant NDA.[41] Instead, the FDA takes at face value the declaration of the NDA filer that listing is appropriate. As a result, an NDA filer acting in bad faith can successfully list patents that do not satisfy the statutory listing criteria. Once listed in the Orange Book, these patents have the same power to trigger a 30-month stay of ANDA approval as any validly listed patent, thereby delaying generic entry and potentially costing consumers millions, or even billions, of dollars without valid cause.

In January of this year, lawsuits relating to Bristol-Myers's alleged monopolization through improper listing of a patent on its branded drug BuSpar – consolidated in the Southern District of New York as *In re Buspirone*[42] – presented the Commission with an opportunity to clarify the *Noerr* doctrine and to have a significant impact on the Commission's ongoing pharmaceutical cases. Specifically, plaintiffs alleged that, through fraudulent patent filings with the FDA, Bristol-Myers caused

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[41] *See* 21 C.F.R. § 314.53(f). *See also* Abbreviated New Drug Application Regulations – Patent and Exclusivity Provisions, 59 Fed. Reg. 50338, 50343 (1994) ("FDA does not have the expertise to review patent information. The agency believes that its resources would be better utilized in reviewing applications rather than reviewing patent claims."); Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28910 (1989) ("In deciding whether a claim of patent infringement could reasonably be asserted . . . the agency will defer to the information submitted by the NDA applicant.").

[42] *In re Buspirone Patent Litigation/In re Buspirone Antitrust Litigation*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) ("*In re Buspirone*"). Some of the same plaintiffs had previously brought suit under the FDC Act, requesting that the court issue an order compelling Bristol-Myers to de-list the objectionable patent. Although plaintiffs prevailed at the district court level, the Federal Circuit reversed that decision, holding that the FDC Act did not provide a private right of action to compel de-listing of a patent from the Orange Book. *See Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323, 1331-32 (Fed. Cir. 2001).

the agency to list the patent in question in the Orange Book, thereby blocking generic competition with its BuSpar product, in violation of Section 2 of the Sherman Act.[43]

As anticipated, Bristol-Myers responded to these allegations by filing a motion to dismiss that raised, principally, a claim of *Noerr-Pennington* immunity. Given the importance of the issue to competition in the pharmaceutical industry, as well as to the Commission's ongoing investigations, the Commission filed an *amicus* brief, opposing the motion to dismiss.[44] On February 14, 2002, the court issued an opinion denying Bristol-Myers's immunity claim and accepting most of the Commission's reasoning on the *Noerr-Pennington* issue.[45]

The court's order was broad, rejecting Bristol-Myers's claim of *Noerr-Pennington* immunity on three independent and alternative grounds. The first, and perhaps most important, of these grounds was that Orange Book filings simply do not constitute protected "petitioning." The court agreed with the Commission's argument that an Orange Book filing is analogous to a tariff filing. In both cases, "the government does not perform an independent review of the validity of the statements, does not make or issue an intervening judgment, and instead acts in direct reliance on the private party's representations."[46] The court also agreed that an Orange Book filing is not incidental to petitioning, holding that Bristol-Myers could have listed its patent in the Orange Book "without subsequently bringing infringement suits . . . [and] could have brought these suits without relying on its Orange Book listing."[47]

The court further concluded that, even if Orange Book filings were to constitute "petitioning," application of two specific exceptions to the *Noerr* doctrine – the *Walker Process* and "sham" exceptions – would preclude a finding of antitrust immunity. Under *Walker Process*,[48] a patent holder may be subject to antitrust liability for attempting to enforce a patent procured through fraudulent misrepresentations to the Patent and Trademark Office ("PTO"). The *Buspirone* court concluded that the Orange Book listing and patent prosecution processes were sufficiently analogous to warrant extension of the *Noerr* exception beyond the PTO context, and that plaintiffs' allegations satisfied *Walker Process*.[49]

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[43] 15 U.S.C. § 2.

[44] Memorandum of Law of *Amicus Curiae* the Federal Trade Commission in Opposition to Defendant's Motion to Dismiss *available at* <http://www.ftc.gov/os/2002/01/ busparbrief.pdf>.

[45] *In re Buspirone, supra* note 42.

[46] 185 F. Supp. 2d at 370.

[47] *Id.* at 372.

[48] *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965).

[49] *In re Buspirone, supra* note 42, at 372-75. Notably, the *Buspirone* court's decision is one of the first to apply the *Walker Process* exception outside the narrow PTO context

Under the "sham" exception, the opponent of *Noerr* immunity must demonstrate that defendant's petitioning conduct – in this case, Bristol Myers's patent filing with the FDA – was "objectively baseless."[50] After an examination of the prosecution history of Bristol-Myers's patent, as well as the specification and claims, the *Buspirone* court concluded that the filing was, indeed, "objectively baseless." The court further observed that Bristol-Myers's argument to the contrary "ignores the law and tries to justify taking property that belongs to the public."[51]

In light of the *Buspirone* decision, and the underlying force of the court's reasoning, the *Noerr-Pennington* doctrine may not prove as large an obstacle to using the antitrust laws to remedy improper Orange Book filings as some may have anticipated. It is worth noting, and indeed emphasizing, that *Buspirone* does not mean that all improper Orange Book filings will give rise to antitrust liability. Any antitrust liability must necessarily be predicated on a clear showing of a violation of substantive antitrust law. But, under *Buspirone*, Orange Book filings are not *immune* from those laws or exempt from their scrutiny.

2. *Biovail (Tiazac)*

Today, the Commission is announcing that it has accepted for public comment an agreement and proposed consent order with Biovail Corporation,[52] settling charges that Biovail illegally acquired an exclusive patent license and wrongfully listed that patent in the Orange Book for the purpose of blocking generic competition to its branded drug Tiazac. This is the Commission's first enforcement action to remedy the effects of an allegedly anticompetitive Orange Book listing.

Prior to the events giving rise to the Commission's complaint, Biovail had already triggered a 30-month stay of FDA final approval of Andrx's generic Tiazac product, by commencing an infringement lawsuit against Andrx. Andrx prevailed in the courts, however, so that by February 2001, the stay would have been lifted. According to the Commission's complaint,[53] Biovail, in anticipation of pending competition from Andrx, undertook a series of anticompetitive actions to trigger a new stay and maintain its Tiazac monopoly. Just before the stay was to terminate, Biovail acquired a newly issued patent from a third party and listed it in the Orange Book as claiming Tiazac – thereby requiring Andrx to re-certify to the FDA under Paragraph IV, and opening the door to Biovail's suit against Andrx for infringement of the new patent and commencement of a second 30-month stay.

According to the Commission's complaint, Biovail knew that the new patent did *not* claim the

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[50] *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49, 60 (1993).

[51] *In re Buspirone*, *supra* note 42, at 376.

[52] *Biovail Corp.* (consent order accepted for public comment, Apr. 19, 2002).

[53] The Commission's complaint against Biovail is available on the FTC's Web site, <http://www.ftc.gov>.

form of Tiazac that it had been marketing, and Biovail did not need this new patent to continue marketing Tiazac without infringement risk. In fact, the FDA later learned that Biovail's position was that the newly listed patent covered a new formulation of Tiazac that Biovail had developed only after it acquired and listed the patent. The newly listed patent did not cover the version of Tiazac that the FDA had approved and that Biovail had been marketing. FDA told Biovail that the new Tiazac formulation therefore lacked FDA approval and that it would de-list the patent from the Orange Book unless Biovail certified that the patent claimed the approved version of Tiazac.

The Commission alleges that Biovail misleadingly represented to the FDA that the new patent claimed existing-and-approved, rather than revised-and-unapproved, Tiazac, to avoid de-listing from the Orange Book and termination of the stay against Andrx.[54] The Commission alleges that Biovail's patent acquisition, wrongful Orange Book listing, and misleading conduct before the FDA were acts in unlawful maintenance of its Tiazac monopoly, in violation of Section 5 of the FTC Act,[55] and that the acquisition also violated Section 7 of the Clayton Act[56] and Section 5 of the FTC Act.

The proposed consent order would require Biovail to divest the illegally acquired patent to its original owner, except as to new product developments outside the Tiazac market; to dismiss its infringement case against Andrx, which would end the stay, thereby allowing entry of generic Tiazac to the benefit of consumers; and to refrain from any action that would trigger another 30-month stay on generic Tiazac entry. Further, the order prohibits Biovail from unlawfully listing patents in the Orange Book and requires Biovail to give the Commission prior notice of acquisitions of patents that it will list in the Orange Book for Biovail's FDA-approved products. These measures should not only remedy Biovail's allegedly unlawful conduct, but also send a strong message that the Commission will act decisively to eliminate anticompetitive practices in the pharmaceutical industry.

C. Settlements Between Generics

Although agreements between first and second generic entrants have attracted significantly less attention to date, they too can raise competitive concerns and may draw antitrust scrutiny in the future. As in the case of agreements between brands and generics, the economic incentives to collude can be

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[54] After learning that Biovail had taken the position that its newly acquired patent covered a formulation of Tiazac developed after acquisition of the patent, the FDA contacted Biovail to determine whether this formulation was the same as the formulation approved under the Tiazac NDA. In response, Biovail submitted a declaration stating simply that its newly acquired patent claimed Tiazac and, therefore, was eligible for listing in the Orange Book. The Commission asserts that this declaration was misleading, because it did not clarify whether the term "Tiazac" as used by Biovail meant FDA-approved Tiazac (as the FDA required) or Biovail's revised form of the product.

[55] 15 U.S.C. § 45.

[56] *Id.* at § 18.

strong. Studies indicate that the first generic typically enters the market at 70-80 percent of the price of the corresponding brand,[57] and rapidly secures as much as a two-thirds market share. The second generic typically enters at an even lower price and, like the first, rapidly secures market share. Collusion between the generics can thus be a means of preventing price erosion in the short term, though it may become substantially less feasible if subsequent ANDAs are approved and additional competitors enter the market.

Two potentially competition-reducing categories of agreements are worth noting. The first involves exclusive distributorship arrangements. A second generic entrant, rather than bringing a competing product to market, might agree to become the exclusive distributor of the first entrant. Such an arrangement would essentially grant the second entrant an agreed-upon share of the market, rather than requiring it to secure that share at the expense of the first entrant through aggressive price competition.

The second involves potential division of market segments. The first entrant might agree to market its product exclusively in one strength, while the second entrant agrees to market its product exclusively in another. Like the exclusive distributorship arrangement, the objective of such an agreement would appear to be *less* vigorous competition, as the agreement would simply grant each company a reciprocal market segment that would otherwise need to be secured through competition on price and other terms.

As with any antitrust case, the analysis would depend on the actual facts, but, at a minimum, such arrangements would arouse significant interest at the Commission.

[57] *See* CBO Study, *supra* note 6; Reiffen and Ward, *supra* note 9, at 22.

IV. Other Commission Efforts to Promote Competition

A. The Commission's 6(b) Study

In light of the serious questions raised by its various generic drug investigations, in October 2000, the Commission proposed a focused industry-wide study of generic drug competition. This study is designed to examine more closely the business relationships between brand-name and generic drug manufacturers in order to understand better the nature and extent of any anticompetitive impediments to the process of bringing new, low-cost generic alternatives to the marketplace and into the hands of consumers. The study will provide a more complete picture of how generic drug competition has developed under the Hatch-Waxman Amendments, including whether agreements between branded and generic drug manufacturers of the types challenged by the Commission are isolated instances or are more typical of industry practices. In addition, the Commission will examine whether particular provisions of the Hatch-Waxman Amendments have operated as intended or have unintentionally enabled anticompetitive strategies that delay or deter the entry of generic drugs into the market.

Last April, the Commission received clearance from the Office of Management and Budget ("OMB") to conduct the study.[58] The Commission has since issued nearly 90 special orders – pursuant to Section 6(b) of the Federal Trade Commission Act[59] – to branded and generic drug manufacturers, seeking information about certain practices that were outlined in the Federal Register notices that preceded OMB clearance to pursue the study.[60] The Commission staff focused each special order on a specific branded pharmaceutical that was the subject of Paragraph IV certifications filed by a potential generic competitor, and, for generic manufacturers, on a specific drug product for which the company had filed an ANDA containing a Paragraph IV certification. Responses from the companies were generally completed by the end of 2001. The Commission staff is currently compiling the information received to provide a factual description of how the 180-day marketing exclusivity and 30-month stay provisions have influenced the development of generic drug competition. We expect that the 6(b) study will be completed, and a report detailing its findings released, sometime this summer.

Among other areas of interest, the Commission staff is also analyzing how often the 180-day marketing exclusivity provision has been used,[61] how it has been triggered (*i.e.*, by commercial

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[58] The Commission was required to obtain OMB clearance before it could begin the study, because the number of special orders to be sent triggered the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. Ch. 35, as amended.

[59] 15 U.S.C. § 46(b).

[60] *See* 65 Fed. Reg. 61334 (Oct. 17, 2000); 66 Fed. Reg. 12512 (Feb. 27, 2001).

[61] Commission staff commented to the FDA on the 180-exclusivity issue in connection with a proposed rulemaking. *See* Marketing Exclusivity Comment, *supra* note 10.

[62] 21 U.S.C. § 355(j)(5)(B)(iv).

marketing or court orders),[62] the frequency with which branded manufacturers have initiated patent litigation, and the frequency with which patent litigation has been settled or litigated to a final court decision. The Commission will use the agreements provided, along with underlying documentation of the reasons for executing the agreement, to examine whether agreements between branded and generic drug manufacturers – or between generics – may have operated to delay generic drug competition. In addition, the study will provide evidence about branded manufacturers' patent listings in the Orange Book, the timeliness of the listings, and how frequently generics challenge those listings. Finally, the study will examine whether the size of a drug product's sales affects the likelihood that a particular strategy will be used to delay generic competition.

A few tentative observations can be made based on the ongoing review of the data received by the Commission, including:

- *The types of potentially anticompetitive practices employed by pharmaceutical companies have changed direction following recent FTC enforcement actions.* The results of the Commission's study, to date, suggest that some pharmaceutical companies – including both brands and generics – have employed a variety of potentially anticompetitive strategies involving Paragraph IV certifications, and that these strategies have changed direction after the FTC's announcement of consent orders in *Abbott/Geneva* and *Hoechst/Andrx*.

- *Grants of marketing exclusivity have increased since the D.C. Circuit's decision in Mova Pharmaceutical Corp. v. Shalala*. The FDA's grant of the 180-day marketing exclusivity has increased substantially since *Mova*, which eased the rules governing how the FDA grants the exclusivity to generic companies.[63] From 1998 to 2001, the FDA has granted the 180-day marketing exclusivity substantially more often than it did from 1984 to 1998.

- *Interim patent agreements[64] appear to be uncommon*. The two patent infringement settlement agreements discussed above – the Abbott/Geneva and Hoechst/Andrx

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[62] 21 U.S.C. § 355(j)(5)(B)(iv).

[63] *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998); *see Granutec, Inc. v. Shalala*, 139 F.3d 889 (4th Cir. 1998). In implementing the 180-day marketing exclusivity provision in the past, the FDA added a requirement that the first ANDA applicant have "successfully defended against a suit for patent infringement" before the applicant is eligible for the 180-day marketing exclusivity period. *Mova* and *Granutec*, however, held that the FDA had exceeded its statutory authority in imposing the "successful-defense requirement" as a prerequisite to obtaining the 180-day marketing exclusivity.

[64] An interim agreement is an agreement in effect until the final determination of the patent litigation.

agreements – were interim agreements. The data reviewed by the Commission to date suggest that this is not the norm. Most agreements have been final agreements that resolve patent litigation.

- *Formulation and method of use patents are the most frequently challenged.* The majority of patents subject to Paragraph IV certifications that result in patent infringement litigation involve formulation and method of use. These are not the patents on the active ingredient contained in the drug product, but the patents on how the product is formulated – for example, into tablets – or how the product will be used to treat certain health problems.

B. Continuing Discussions with FDA

In addition to its independent efforts, the Commission continues to work with FDA to ensure robust competition from generic drugs. Most recently, these efforts have included a Citizen Petition filed by Commission staff to clarify the proper content of Orange Book listings. The Commission staff also participated in the FDA's January 30, 2002, "symposium" on Hatch-Waxman. This event provided a forum for representatives from the leading trade associations of branded and generic drug manufacturers – the Pharmaceutical Researchers and Manufacturers of America ("PhRMA") and the Generic Pharmaceuticals Association ("GPhA") – to present their concerns to FDA and advocate specific regulatory reforms. The Commission staff participated in the questioning of the PhRMA and GPhA representatives and discussed with FDA the potential competitive impact of various regulatory approaches. Finally, the Commission staff continues to bring concerns to the attention of the FDA informally in order to encourage the implementation of the Hatch-Waxman drug approval process with an eye toward competition and consumer welfare (in addition to the traditional goals of safety and efficacy).

V. Conclusion

Thank you for this opportunity to share the Commission's views on competition in the pharmaceutical industry. As you can see from this testimony, the Commission has been and will continue to be very active in protecting consumers from anticompetitive practices that inflate drug prices. The Commission looks forward to working closely with the Committee, as it has in the past, to ensure that competition in this critical sector of the economy remains vigorous. In keeping with this objective, the Commission will likewise endeavor to ensure that the careful Hatch-Waxman balance – between promoting innovation and speeding generic entry – is scrupulously maintained.